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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,588	08/22/2003	Brian P. Watschke	240993US25	9478
22850	7590	05/23/2006		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER LUSTUSKY, SARA	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,588

Applicant(s)

WATSCHKE ET AL.

Examiner

Sara Lustusky

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 14, 16, 17, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-12, 15 and 18 is/are rejected.
- 7) ☒ Claim(s) 2, 5, 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/22/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/8/03 3/26/04 6/8/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities:
3. The acronym "SUI" in line 4 of paragraph [0003] is not defined in the text
4. There is missing text, "application serial No. 10/____, ____" in line 5 of paragraph [0040]. Also, the character "400" disclosed in line 3 of paragraph [0039] represents the vaginal incision in Figure 4. Previously the character (400) was used to reference the suprapubic incisions, as seen in line 9 of paragraph [0038], and character (404), as seen in line 11 of paragraph [0040], was used to in reference to the vaginal incision.
5. In line 1 of paragraph [0008]; "case" should read -- cases --.
6. In line 5 of paragraph [0010], the phrase "to assure that the sling doe not get done" is unclear. Appropriate correction is required.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "line A" in line 3 of paragraph [0035] and "420" in line 8 of paragraph [0046]. In addition to this, the drawings include the following reference character(s) not mentioned in the description: "402" as seen in Figures 5 and 6 and "42" as seen in Figure 9 and 10.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20" has been used to designate both the vagina and the lower sheath. This may be seen in Figures 1, 2, 4, 6 and 7. Furthermore, reference characters "20" and "200" have both been used to designate the vagina. This can be seen in Figures 1, 2, 4, 6 and 7.

9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The recitation in line 2 stating, "The first upper sheath can be used on either the left or right side of the patient" is unclear as the sheath is to be used on the upper regions of the sling.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 3, 4, 7-9, 14, 15, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 3: the use of the pronoun "its" is unclear.

15. Claim 4: "the mesh" is recited in line 4. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 7: It is unclear what is meant by the recitation "assisting in asserting the sling assembly" in line 1.

Art Unit: 3735

17. Claim 8: It is unclear what is meant by the recitation "the central portion of the sling is free of any overlapping sheath portions" in line 5. It has been disclosed in claim 1 that each upper sheath envelops an upper portion of the sling and that the lower sheath envelopes the central portion of the sling. It is unclear how the central portion of the sling is free of overlapping sheath portions if the upper sheaths and lower sheath have overlapping portions as recited in claim 8 if the sling is enveloped by this sheath configuration.

18. Claim 14: "the mesh" is recited in line 3. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 15: "the mesh" is recited in line 2. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 18: "the mesh" is recited in line 2. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 19: "the mesh" is recited in line 2. There is insufficient antecedent basis for this limitation in the claim. Further regarding claim 19, the "spacer" recited in line 2 lacks antecedent basis. There is no disclosure that a spacer has been placed or exists in claims 13 and 19 prior to this recitation.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

23. Claims 1, 3 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Gellman et al. (PGPUB US 2004/0039246 A1).

24. Claim 1: Gellman et al. (PGPUB US 2004/0039246 A1) teaches a sling assembly, comprising:

- a. A surgical sling (2) configured to be implanted during a surgical sling procedure, and including first (14) and second regions (24) and a central portion (logically between the first and second regions);
- b. A removable sheath assembly situated about the surgical sling (as seen in Figure 11a), the removable sheath assembly comprising; first and second upper sheaths (the examiner interprets this limitation to include sheaths that cover a sling on the right and/or left portions), described in line 2 of paragraph [0046], a lower sheath (310) (as seen in Figure 11a), the lower sheath (310) configured to be situated about the central portion of the surgical sling, as described in line 2 of paragraph [0037], (as seen in Figure 11a) and to be in cooperative association

Art Unit: 3735

with both the first and second upper sheaths, described in lines 1-5 of paragraph [0046].

25. Claim 3: Gellman et al. (PGPUB US 2004/0039246 A1) teaches the sling assembly of claim 1, wherein the lower sheath (310) defines an interior portion that envelopes the surgical sling (300) and an exterior portion which has first and second faces (as seen in Figures 11a-11b), the first face configured to be placed adjacent to a patient's urethra, described in line 2 of paragraph [0039] (as seen in Figures 9a-9c), and the first face includes a score places longitudinally along its length (as seen in Figure 11b).

26. Claim 12: Gellman et al. (PGPUB US 2004/0039246 A1) teaches that the sling in the sling assembly of claim 1 is elastic, as described in lines 1-7 of paragraph [0086].

27. While Gellman et al. (PGPUB US 2004/0039246 A1) does disclose the use of a protective sleeve, the type of sleeve or sheath to be used is not specified. However, Gellman et al. (PGPUB US 2004/0039246 A1) discloses that the sling may be encased wholly or partly within a protective sleeve as described in line 2 of paragraph [0046]. Furthermore, it is commonly known in the art to use a two-part sleeve or sheath over a medical sling during surgery to reduce the risk of injury to the surrounding tissue during implantation of a sling assembly. Two-part sheaths are often perforated and able to be torn apart during removal, or each part may be completely independent of each other. These variations and others are commonly known in the art to ease sheath removal and to minimize the disturbance of the implanted sling during sheath removal. One such example may be seen in Gellman et al. (PGPUB US 2002/0156488 A1). Gellman teaches a first upper sheath (20A) configured to be situated about the first region of the

Art Unit: 3735

surgical sling (10), and the second upper sheath (20B) configured to be situated about the second region (12) of the surgical sling (10) (as seen in the embodiment shown in Figure 7B).

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (PGPUB US 2004/0039246 A1) in view of Gellman et al. (PGPUB US 2002/0156488 A1). Gellman et al. (PGPUB US 2004/0039246 A1) teaches a sling assembly including upper and lower sheaths to be implanted during a surgical sling procedure but does not teach the use of a spacer with the sling assembly.

30. Gellman et al. (PGPUB US 2002/0156488 A1) teaches the use of a spacer (100) configured to be placed between the surgical sling (10) and the patient's urethra (999) (as seen in Figures 5A, 5E, 5F), described in lines 13-15 of paragraph [0160].

31. It would have been obvious to one of ordinary skill in the art to use the spacer of Gellman et al. (PGPUB US 2002/0156488 A1) with the sling assembly of Gellman et al. (PGPUB US 2004/0039246 A1) because a spacer is helpful in adjusting the tension and position of the sling during its placement, described in lines 6 and 23 of paragraph [0160] of Gellman et al. (PGPUB US 2002/0156488 A1). The amount of tension a sling

Art Unit: 3735

puts on the surrounding tissue is important with respect to the assembly's effectiveness after implantation.

Allowable Subject Matter

32. Claims 2, 5, and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 2 defines over the art because none of the prior art of record shows a central sheath with a first face including a kiss cut. Claim 5 defines over the art because none of the prior art of record shows a removal assembly operatively associated with a lower sheath. Claim 6 defines over the art because none of the prior art of record shows the removal assembly defined by claim 5 with a tube situated within a lower sheath and a suture operatively associating the tube and a tab.

33. Claims 4, 7-10, 15 and 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

34. Claims 13, 14, 16, 17, 19, and 20 are allowable over the prior art of record. Claim 13 defines over the art because none of the prior art of record shows a method for implanting a sling comprising the steps of providing a sheath assembly including two upper sheaths and a lower sheath wherein the lower sheath is removed via at least one vaginal incision and the upper sheaths are removed via at least one suprapubic incision.

Art Unit: 3735

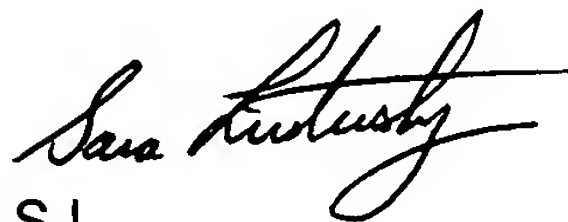
Claim 20 defines over the art because the prior art of record does not show the removal of a lower sheath via a vaginal incision.

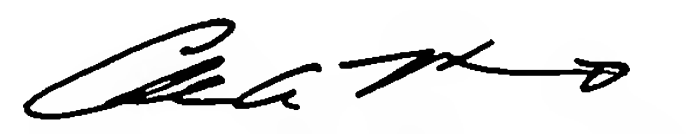
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


S.L.


Charles A. Marmor, II
SPE, Art Unit 3735